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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,088	07/18/2003	Robert P. Bennett	0942.5450007/RWE/BJD/SJE	1853

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EXAMINER

HORNING, MICHELLE S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,088

Applicant(s)

BENNETT ET AL.

Examiner

Michelle Horning

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 18, 21, 23 and 28-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19-20, 22, and 24-27 is/are rejected.
- 7) ☒ Claim(s) 25-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to communication filed 1/17/2006. Please note that the application has been transferred to another examiner. All further correspondences regarding this application should be directed to Michelle Horning of AU 1648.

The status of the claims is as follows: claims 17, 19-20, 22, 24-27 are under current examination and claims 1-16, 18, 21, 23 and 28-43 are drawn to non-elected matter.

Applicant's election without traverse of Group I and species (ii) and (viii) in the reply filed on 1/17/2006 is acknowledged.

IDS

The Information Disclosure Statement filed 8/28/2006 and only one filed 8/10/2006 has been considered

One Information Disclosure Statement filed 8/10/2006 has not been fully considered. This submission cites approximately 500 documents requiring a listing on an about 180 page PTO-1449. A review of the first 20 publications revealed only 5 deemed to be material to patentability. For example, publications drawn to bile acid enzymes, neuropeptide Y and leptin are not related to the material of the instant application. In view of the very low percentage of references material to patentability in the sampled documents reviewed, the submission is not in compliance with 37 CFR 1.56 and 1.98. Accordingly, the remaining references will not be considered.

Claim Objections

Claim 25 is objected to because of the following informalities: in the recitation "between the recombination site", site should be sites. Appropriate correction is required.

Claim 26 is objected to because of the following informalities: in the recitation "consisting a sequence", the word of is missing. Appropriate correction is required.

Claim Rejections

35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 19-20, 22 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 17 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear by what is meant by "a first and a second recombination site that do not substantially recombine with each other".

35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 19-20, 22, 24-27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Douglas et al (2001). The limitations of the above claims are:

1. A method of making a recombinant virus comprising
 - a. a nucleic acid molecule comprising all or a portion of one or more viral genomes and 2 recombination sites that do not recombine with each other,
 - b. contacting the above nucleic acid with a second nucleic acid molecule comprising a sequence of interest flanked by 2 recombination sites in which each site can uniquely recombine with one of two sites above, and
 - c. introducing the molecule of step b into a cell;
2. the method above in which the first molecule is consists of a retroviral, lentiviral and RNA virus genome;
3. the method above in which the molecule is a plasmid comprising an origin of replication and a selectable marker;
4. the method above in which the sequence of interest comprises one or more polypeptides; and
5. the method above in which the first molecule is digested with a restriction enzyme that cleaves the first molecule at a site that is between the recombination sites.

Douglas et al meet all of the above limitations. This prior art reference teaches an HIV-based vector combined with the vesicular stomatitis virus glycoprotein as the gene of interest for the efficient transduction of cells (see Overview Summary, Materials and Methods and *Transduction of human cell lines* under Results). Of note, HIV is an example of a retrovirus, lentivirus and RNA virus. Further, the plasmid comprises an origin of replication and a selectable marker, or more specifically, an LTR and an EGFP (see Figure 1 and Materials and Methods). Lastly, Douglas et al describes a single *EcoRI* site in which digestion leads to a single cut inside the vector (page 404, see *Comparison of vector copy number and transgene expression*). Thus, because all of the above limitations have been met, the above claims are rejected.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

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access to the Private PAIR system, contact the Electronic Business Center (EBC) at
866-217-9197 (toll-free).


Michelle Horning
Patent Examiner



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